



INFORMATION CITED BY APPLICANTS THAT MAY BE MATERIAL TO THE
PROSECUTION OF THE SUBJECT APPLICATION

Applicants: R.J. Speirs et al. Attorney Docket No. CHIR122149

Application No.: 10/743,529

Filed: December 22, 2003

Title: METHODS AND UNIT DOSE FORMULATIONS FOR THE INHALATION
ADMINISTRATION OF AMINOGLYCOSIDE ANTIBIOTICS

U.S. PATENT DOCUMENTS

*Examiner Initials	Cite No.	Document No.	Kind Code	Date (mm/dd/yyyy)	Name
<i>BS</i>	A	5,508,269	A	04/16/1996	Smith et al.
<i>BS</i>	B	6,387,886	B1	05/14/2002	Montgomery et al.
<i>BS</i>	U1	6,083,922	A	07/04/2000	Montgomery

FOREIGN PATENT DOCUMENTS

*Examiner Initials	Cite No.	Document No.	Kind Code	Publication Date (mm/dd/yyyy)	Country	English Abstract Provided	Translation Provided
<i>BS</i>	F1	WO 00/35461	A1	06/22/2000	WO		
<i>BS</i>	F2	WO 98/43650	A1	10/08/1998	WO		

OTHER INFORMATION
(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initials	Cite No.	Information
<i>BS</i>	O01	"TOBI® Tobramycin Solution for Inhalation," <i>Prescribing Information</i> , CHIRON Corporation, Emeryville, Calif., April 2001, 4 pp.
<i>BS</i>	O02	Standaert, T.A., et al., "The Choice of Compressor Effects the Aerosol Parameters and the Delivery of Tobramycin From a Single Model Nebulizer," <i>J. Aerosol Medicine</i> 13(2):147-153, 2000.
<i>BS</i>	O03	"PathoGenesis Inks Deal With AeroGen," <i>Puget Sound Business Journal</i> , ©2000 American City Business Journals Inc., < http://seattle.bizjournals.com/seattle/stories/2000/02/daily15.html > [retrieved April 15, 2004].

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS, P.C.
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100



- 004 Ho, S.L., and A.L. Coates, "Effect of Dead Volume on the Efficiency and the Cost to Deliver Medications in Cystic Fibrosis With Four Disposable Nebulizers," *Can. Respir. J.* 6(3):253-260, 1999.
- 005 Kendrick, A.H., et al., "Selecting and Using Nebuliser Equipment," *Thorax* 52(Suppl 2):S92-S101, 1997.
- 006 Coates, A.L., et al., "The Choice of Jet Nebulizer, Nebulizing Flow, and Addition of Albuterol Affects the Output of Tobramycin Aerosols," *Chest* 111(5):1206-1212, 1997.
- 007 Weber, A., et al., "Effect of Nebulizer Type and Antibiotic Concentration on Device Performance," *Pediatric Pulmonology* 23:249-260, 1997.
- 008 Touw, D.J., et al., "Pharmacokinetics of Aerosolized Tobramycin in Adult Patients With Cystic Fibrosis," *Antimicrobial Agents and Chemotherapy* 41:184-187, 1997.
- 009 Faurisson, F., et al., "Étude Comparative sur les Performances et l'Ergonomie de Nébuliseurs dans la Mucoviscidose," *Rev. Mal. Resp.* 13:155-162, 1996.
- 010 Nikolaizik, W.H., et al., "Bronchial Constriction After Nebulized Tobramycin Preparations and Saline in Patients With Cystic Fibrosis," *Eur. J. Pediatrics* 155:608-611, 1996.
- 011 Weber, A., et al., "Tobramycin Serum Concentrations After Aerosol and Oral Administration in Cystic Fibrosis," *Am. J. Therapeutics* 2:81-87, 1995.
- 012 Weber, A., et al., "Nebulizer Delivery of Tobramycin to the Lower Respiratory Tract," *Pediatric Pulmonology* 17:331-339, 1994.
- 013 Cooney, G.F., et al., "Absolute Bioavailability and Absorption Characteristics of Aerosolized Tobramycin in Adults With Cystic Fibrosis," *Clin. Pharmacol.* 34:255-259, 1994.
- 014 Littlewood, J.M., et al., "Aerosol Antibiotic Treatment in Cystic Fibrosis," *Archives of Disease in Childhood* 68:788-792, 1993.
- 015 Le Conte, P., et al., "Lung Distribution and Pharmacokinetics of Aerosolized Tobramycin," *Am. Rev. Respir. Dis.* 147:1279-1282, 1993.
- 016 Ramsey, B.W., et al., "Efficacy of Aerosolized Tobramycin in Patients With Cystic Fibrosis," *New England J. Med.* 328:1740-1746, 1993.
- 017 Makhoul, I. R., et al., "Antibiotic Treatment of Experimental *Pseudomonas aeruginosa* Pneumonia in Guinea Pigs: Comparison of Aerosol and Systemic Administration," *J. Infectious Diseases* 168:1296-1299, 1993.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{mc}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100



Valcke, Y.J., and R.A. Pauwels, "Pharmacokinetic Evaluation of Tobramycin in the Alveolar Lining Fluid of the Rat After Endotracheal Administration," *Am. Rev. Respir. Dis.* 144:1199-1201, 1991.

O19 Smith, A.L., et al., "Safety of Aerosol Tobramycin Administration for 3 Months to Patients With Cystic Fibrosis," *Pediatric Pulmonology* 7:265-271, 1989.

O20 MacLusky, I.B., et al., "Long-Term Effects of Inhaled Tobramycin in Patients With Cystic Fibrosis Colonized With *Pseudomonas aeruginosa*," *Pediatric Pulmonology* 7:42-48, 1989.

O21 Steinkamp, G., et al., "Long-Term Tobramycin Aerosol Therapy in Cystic Fibrosis," *Pediatric Pulmonology* 6:91-98, 1989.

O22 Durrani, F.K., et al., "Evaluation of a New, Shorter Method of Administration of Adrenergic Aerosols in the Treatment of Asthma," *Annals of Allergy* 61:147-150, 1988.

O23 Geller, D.E., et al., "Efficiency of pulmonary administration of tobramycin solution for inhalation in cystic fibrosis using an improved drug delivery system," *Chest* 123:28-36, 2003.

Examiner

Mark Sackey

Date Considered

8/5/04

*Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicants.

TFB:snh/tmm/ctg

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100